

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 39042-0037
INTERNATIONAL APPLICATION NO. PCT/GB2004/004740	INTERNATIONAL FILING DATE November 10, 2004	U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/578692
TITLE OF INVENTION DRY RECOMBINANT HUMAN ALPHA 1-ANTITRYPSIN FORMULATION		
APPLICANT(S) FOR DO/EO/US Rajiv NAYAR, Mark G. MANNING, Philip J. BARR, Philip PEMBERTON, Ian C. BATHURST, Helen GIBSON		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
<p>1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a submission under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a submission under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below.</p> <p>4. <input type="checkbox"/> The US has been elected (Article 31).</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau). b. <input checked="" type="checkbox"/> has been communicated by the International Bureau. (copy of PCT/IB/308 attached). c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). <p>6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).</p> <ul style="list-style-type: none"> a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). <p>7. <input checked="" type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <ul style="list-style-type: none"> a. <input checked="" type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made. <p>8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4))</p> <p>10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p>		
<p>Items 11 to 20 below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p> <p>20. <input checked="" type="checkbox"/> Other items or information: return postcard</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. (if known, see 37 CFR 1.5) 10/578692		INTERNATIONAL APPLICATION NO. PCT/GB2004/004740	ATTORNEY'S DOCKET NUMBER 39042-0037
The following fees have been submitted		CALCULATIONS PTO USE ONLY	
21. <input checked="" type="checkbox"/> Basic national fee.....		\$300	\$ 300
22. <input checked="" type="checkbox"/> Examination fee If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)..... All other situations.....		\$100 \$200	\$ 200
23. <input checked="" type="checkbox"/> Search fee Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority..... International Search Report prepared and provided to the Office..... All other situations.....		\$100 \$400 \$500	\$ 500
TOTAL OF 21, 22 and 23 =		\$ 1000	
<input checked="" type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.			
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE
16 - 100 =	0 /50 =	0	x \$250
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).		\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE
Total claims	21 - 20 =	1	x \$ 50
Independent claims	1 - 3 =	0	x \$200
MULTIPLE DEPENDENT CLAIM(S) (if applicable)		+ \$360	\$ 0
		TOTAL OF ABOVE CACULATIONS =	\$ 1050
<input checked="" type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.			
		SUBTOTAL =	\$ 525
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).		+ \$ 0	
		TOTAL NATIONAL FEE =	\$ 525
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property		+ \$ 0	
		TOTAL FEES ENCLOSED =	\$ 525
		Amount to be refunded:	\$
		Amount to be charged:	\$ 525
a. <input type="checkbox"/>	A check in the amount of \$ _____ to cover the above fees is enclosed.		
b. <input checked="" type="checkbox"/>	Please charge my Deposit Account No. <u>08-1641</u> in the amount of \$ <u>525</u> to cover the above fees. A duplicate copy of this sheet is enclosed.		
c. <input checked="" type="checkbox"/>	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>08-1641</u> . A duplicate copy of this sheet is enclosed.		
d. <input type="checkbox"/>	Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.		
NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.			
SEND ALL CORRESPONDENCE TO:			
Heller Ehrman LLP			
275 Middlefield Road			
Menlo Park, CA 94025-3506			
 SIGNATURE Leslie Mooi NAME 37,047 REGISTRATION NUMBER			

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TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER GJE-7462CXC1
INTERNATIONAL APPLICATION NO. PCT/GB2004/004740	INTERNATIONAL FILING DATE November 10, 2004	U.S. APPLICATION NO. (If known, see 37 CFR 1.5) 10/578692
TITLE OF INVENTION Dry Recombinant Human Alpha 1-Antitrypsin Formulation		
APPLICANT(S) FOR DO/EO/US Rajiv Nayar, Mark G. Manning, Philip J. Barr, Philip A. Pemberton, Ian C. Bathurst, Helen Gibson		
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:		
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Items 11 to 20 below concern document(s) or information included:		
<p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input checked="" type="checkbox"/> A preliminary amendment.</p> <p>14. <input type="checkbox"/> An Application Data Sheet under 37 CFR 1.76.</p> <p>15. <input type="checkbox"/> A substitute specification.</p> <p>16. <input type="checkbox"/> A power of attorney and/or change of address letter.</p> <p>17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.</p> <p>18. <input type="checkbox"/> A second copy of the published International Application under 35 U.S.C. 154(d)(4).</p> <p>19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).</p>		

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

AP20 Rec'd PCT/PTO 10 MAY 2006

PTO-1390 (Rev. 07-2005)

Approved for use through 3/31/2007. OMB 0651-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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U.S. APPLICATION NO. (if known, see 37 CFR 1.15) 10/578692	INTERNATIONAL APPLICATION NO. PCT/GB2004/004740	ATTORNEY'S DOCKET NUMBER GJE-7462CXC1
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20. Other items or information:

Certificate of Mailing by Express Mail

Copy of first page of published PCT application WO 2005/047323 A1

The following fees have been submitted			CALCULATIONS	PTO USE ONLY
21. <input checked="" type="checkbox"/> Basic national fee (37 CFR 1.492(a))		\$300	\$ 300.00	
22. <input checked="" type="checkbox"/> Examination fee (37 CFR 1.492(c))			\$ 200.00	
If the written opinion prepared by ISA/US or the international preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....	\$0			
All other situations.....	\$200			
23. <input checked="" type="checkbox"/> Search fee (37 CFR 1.492(b))				
If the written opinion of the ISA/US or the International preliminary examination report prepared by IPEA/US indicates all claims satisfy provisions of PCT Article 33(1)-(4).....	\$0			
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority.....	\$100			
International Search Report prepared by an ISA other than the US and provided to the Office or previously communicated to the US by the IB.....	\$400			
All other situations.....	\$500			
TOTAL OF 21, 22 and 23 =			\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing in compliance with 37 CFR 1.821(c) or (e) or computer program listing in an electronic medium) (37 CFR 1.492(j)).				
The fee is \$250 for each additional 50 sheets of paper or fraction thereof.				
Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE	
25 - 100 =	0 /50 =		x \$250	\$
Surcharge of \$130.00 for furnishing any of the search fee, examination fee, or the oath or declaration after the date of commencement of the national stage (37 CFR 1.492(h)).			\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$
Total claims	21 - 20 =	1	x \$ 50	\$ 50.00
Independent claims	1 - 3 =	0	x \$200	\$
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$
TOTAL OF ABOVE CALCULATIONS =			\$ 950.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.			\$	
SUBTOTAL =			\$ 950.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(i)).			\$	
TOTAL NATIONAL FEE =			\$ 950.00	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property			\$	
TOTAL FEES ENCLOSED =			\$ 950.00	
			Amount to be refunded:	\$
			Amount to be charged	\$

10/578692

Approved for use through 3/31/2007. GPO: 2007-002-0021

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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IAP20 Rec'd 10 MAY 2006

- a. A check in the amount of \$ _____ to cover the above fees is enclosed.
- b. Please charge my Deposit Account No. 19-0065 in the amount of \$ 950.00 to cover the above fees. A duplicate copy of this sheet is enclosed.
- c. The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 19-0065. A duplicate copy of this sheet is enclosed.
- d. Fees are to be charged to a credit card. **WARNING:** Information on this form may become public. **Credit card information should not be included on this form.** Provide credit card information and authorization on PTO-2038.

NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.

SEND ALL CORRESPONDENCE TO:

CUSTOMER NUMBER

23557

May 10, 2006

Date

David Saliwanchik

SIGNATURE

David R. Saliwanchik

NAME

31,794

REGISTRATION NUMBER

10/578692

Patent Application
Docket No. GJE-7462CXC1

AP20 Rec'd PCT/PTO 10 MAY 2006

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s) : Rajiv Nayar, Mark G. Manning, Philip J. Barr, Philip A. Pemberton,
Ian C. Bathurst, Helen Gibson

Docket No. : GJE-7462CXC1

For : Dry Recombinant Human Alpha 1-Antitrypsin Formulation

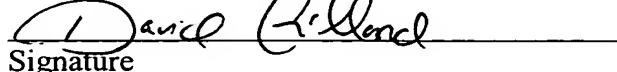
Mail Stop PCT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF MAILING BY EXPRESS MAIL (37 CFR §1.10)

Express Mail **EQ543119244US** Date of Deposit: May 10, 2006

I hereby certify that the attached Transmittal Letter to the United States Designated/Elected Office (DO/EO/US) with copies as required for authorization for use of Deposit Account No. 19-0065; Preliminary Amendment; and unsigned Declaration (37 CFR §1.63) and Power of Attorney are being deposited with the United States Postal Service Express Mail Post Office to Addressee service under 37 CFR §1.10 on the date indicated above and are addressed to: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

David Gilland
Name of person mailing paper


Signature